



Organization of Agreement States

Stanley Fitch, Chair, New Mexico
Jared Thompson, Chair-Elect, Arkansas
Pearce O'Kelley, Past Chair, South Carolina
Gary Robertson, Treasurer, Washington
Kenneth Weaver, Secretary, Colorado

September 3, 2004

DOCKETED
USNRC

Annette L. Vietti-Cook, Secretary
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

September 29, 2004 (4:26PM)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

Attention: Rulemakings and Adjudications Staff

PRM - 35-17

Dear Mrs. Vietti-Cook:

On behalf of the Organization of Agreement States (OAS) and pursuant to 10 CFR 2.802, the enclosed petition is submitted to the U.S. Nuclear Regulatory Commission (NRC) to amend 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. The purpose of this petition is to define and specify the minimum number of didactic (classroom and laboratory) training hours for the Authorized Nuclear Pharmacist and the Authorized Users identified in these sections.

The OAS has developed a Position Statement regarding 10 CFR Part 35 Training and Education requirements identified in 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. In the current rule, the minimum numbers of didactic training hours for radiation safety training are not specified or separated from the total training hours. The current Subpart J does specify a minimum number of classroom and laboratory training hours and supervised work experience.

The Training and Education requirements of Part 35 have been designated as a Category B by the NRC, for Agreement State compatibility in an attempt to provide nationwide "consistency and uniformity." The higher the compatibility classification, the more prescriptive, and more specific the rule text must be to ensure that all Agreement States and NRC Regions be uniform and consistent. The lack of clearly defined didactic training hours for these rule sections weakens the current rule's consistency and uniformity.

The OAS believes that the need for specified didactic training hours is a radiation safety issue rather than a "practice of medicine" issue. Radiation safety for the patient and the occupational radiation workers may likely be compromised. A majority of radiation safety principles and procedures are learned during this important and necessary classroom and laboratory training.

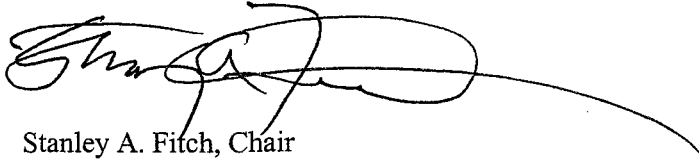
The OAS Executive Board unanimously approved the Position Statement and presented it to the membership for approval. An overwhelming majority (30 of 33) of the Agreement States approved this Position Statement and Petition for Rulemaking. Enclosed is the originally signed OAS Position Statement from the Agreement States requesting this petition for rulemaking.

*Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky,
Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico,
New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee,
Texas, Utah, Washington, Wisconsin*

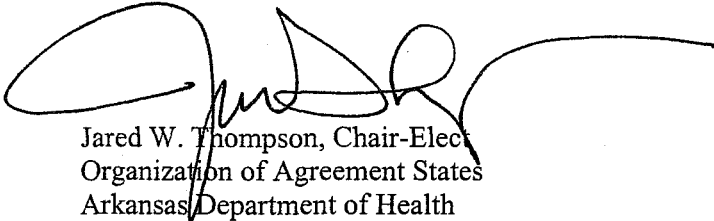
The petitioner, OAS, requests that the Commission define and specify the minimum number of didactic training hours for the authorized users identified in 10 CFR 35.55, 10 CFR 35.190, 10 CFR 35.290 and 10 CFR 35.390. The clarification of the rule is necessary to ensure consistency and uniformity for medical users nationwide. The Commission should work closely with the stakeholders and Agreement States to achieve a resolution to this problem with the training and education requirements.

It is the desire of OAS to promote an NRC/Agreement State partnership for the development and implementation of uniform and consistent regulations that promote and protect public health and safety. Thank you for your consideration.

Sincerely,



Stanley A. Fitch, Chair
Organization of Agreement States
P.O. Box 913
Sandia Park, New Mexico 87047-0913



Jared W. Thompson, Chair-Elect
Organization of Agreement States
Arkansas Department of Health
4815 W. Markham, Mail Slot 30
Little Rock, Arkansas 72205

cc: Kenneth L.K. Weaver, Secretary
Organization of Agreement States

Paul H. Lohaus, Director
NRC Office of State and Tribal Programs

*Alabama, Arizona, Arkansas, California, Colorado, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky,
Louisiana, Maine, Maryland, Massachusetts, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico,
New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Rhode Island, South Carolina, Tennessee,
Texas, Utah, Washington, Wisconsin*



Organization of Agreement States

PETITION FOR RULEMAKING

The Organization of Agreement States (OAS) submits this petition for rulemaking pursuant to 10 CFR 2.802. It is patterned after the layout and structure of previously submitted petitions accepted by the U.S. Nuclear Regulatory Commission (NRC). The petitioner request the NRC, following notice and opportunity for comment, amend 10 CFR Part 35.55, *Training for an authorized nuclear pharmacist*, 10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, 10 CFR 35.290, *Training for imaging and localization studies*, and 10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive is required*, to define and specify the number of didactic (classroom and laboratory) training hours in radiation safety required for authorized users and pharmacists.

I. STATEMENT OF PETITIONER'S INTEREST

The OAS is a nonprofit, voluntary, scientific and professional society incorporated in the District of Columbia. The membership of OAS consists of state radiation control directors and staff from the 33 Agreement States who are responsible for implementation of their respective radioactive materials programs. The purpose of the OAS is to provide a mechanism for these Agreement States to work with each other and with the NRC on regulatory issues associated with their respective agreements.

Agreement States are those states that have entered into an effective regulatory discontinuance agreement with the NRC under subsection 274b. of the Atomic Energy Act (AEA). The role of the Agreement States is to regulate most types of radioactive material in accordance with the compatibility requirements of the AEA. These types of radioactive materials include source material (uranium and thorium), reactor fission byproducts, and quantities of special nuclear materials (SNM) not sufficient to form a critical mass. The NRC periodically reviews the performance of each Agreement State to assure compatibility with NRC's regulatory requirements.

Agreement States issue radioactive material licenses, promulgate regulations, and enforce those regulations under the authority of each individual state's laws. The Agreement States exercise their licensing and enforcement actions under direction of their governors in a manner that is compatible with the licensing and enforcement programs of the NRC. The Agreement States currently license and regulate approximately 16,800 radioactive materials licenses, whereas the NRC regulates approximately 4,400 licenses.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

II. BACKGROUND

The NRC revised 10 CFR Part 35, *Medical Use of Byproduct Material*, on April 24, 2002 to make the rule more risk-informed and performance based. The revised training and experience requirements specified in 35.55 (Authorized Nuclear Pharmacists), 35.290 (Authorized Users for Imaging and Localization Studies), and 35.390 (Authorized Users for unsealed byproduct material which requires a written directive) include completion of 700 hours of training and experience. The revised training and experience requirements specified in 35.190 (Authorized Users for uptake, dilution and excretion studies) include completion of 60 hours of training and experience. These sections require said training and experience to include “classroom and laboratory training” and supervised “work experience”; however, there is no specified breakdown, or division, of these hours. The current rule specified in Subpart J, does specify a breakdown of hours between classroom and laboratory training and supervised work experience.

10 CFR Part 35.55, *Training for an authorized nuclear pharmacist*, requires the accepted boards to require the same 700 total hours of didactic and supervised practical experience hours as specified in 35.55.b for the alternative pathway. It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, requires the accepted boards to require the same 60 total hours specified in the alternative pathway (35.190.c). The wording of the text refers to the description of the hours in 35.190.c.1. Paragraph 35.190.c.1 states, “Has completed 60 hours of training and experience in basic radionuclide handling techniques....”. It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.290, *Training for imaging and localization studies*, requires the accepted boards to require the same 700 hours specified in the alternative pathway (35.290.c). The wording of the text refers to the description of the hours in 35.290.c.1. Paragraph 35.290.c.1 states “Has completed 700 hours of training and experience in basic radionuclide handling techniques...” It does not specify a breakdown of the didactic training hours in radiation safety.

10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive is required*, requires the accepted boards to require the same 700 hours specified in the alternative pathway (35.390.b). The wording of the text refers to the description of the hours in 35.390.b.1. Paragraph 35.390.b.1 states “Has completed 700 hours of training and experience in basic radionuclide handling techniques...” It does not specify a breakdown of the didactic training hours in radiation safety.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

III. Proposed Actions

10 CFR Part 35.55, *Training for an authorized nuclear pharmacist*, 10 CFR 35.190, *Training for uptake, dilution, and excretion studies*, 10 CFR 35.290, *Training for imaging and localization studies*, and 10 CFR 35.390, *Training for use of unsealed byproduct material for which a written directive* be amended to define and specify the number of didactic training hours in radiation safety for these pharmacists and medical authorized users.

It is recommended that the training and experience requirements for 35.55, 35.190, 35.290, and 35.390 be revised to specify a breakdown of the total training hours into didactic (classroom and laboratory) training and supervised work experience. This will clarify that radiation safety, which is clearly within the Agreement States and NRC's purview, rather than clinical skills, are the focus of the regulatory requirements.

The amended rules will ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists and ensure consistency and uniformity of training requirements nationwide.

IV. RATIONALE FOR THE CHANGES

OAS believes that the need for specific didactic training hours is not a "practice of medicine issue" but it is a radiation safety training issue.

The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35. Since radiation safety is the goal of these related regulations, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". In addition, proper didactic training programs will better prepare the individual for out of the ordinary occurrences that are not likely to be seen during supervised work experience. An appropriate didactic training program should supplement the supervised work experience portion so that the individual understands how radiation safety integrates into the practice of medicine. If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety that person cannot effectively supervise the safe use of radioactive material.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

While the OAS is unaware of any documentation of major inconsistencies in the Agreement State implementation of the old Training and Experience requirements, the Training and Experience requirements of the revised Part 35 have been designated as "Category B" for Agreement State compatibility in an attempt to provide nationwide "consistency and uniformity" of authorized user credentialing. The higher the compatibility classification, the more prescriptive, and more specific the rule text must be to ensure that all Agreement States and NRC Regions can be uniform and consistent. The lack of clearly defined didactic training hours for these authorized users weakens the rule's consistency and uniformity.

By not specifying a minimum number of didactic training hours in these paragraphs, radiation safety is likely compromised, leading to a weakening of the effectiveness of Part 35 to adequately assure the radiation safety of the patient, the occupationally exposed worker, and the public. In addition, the effort to develop a consistent and uniform set of standards has been weakened. Consistency is necessary so that Agreement States and NRC Regional offices can accept each other's approved authorized users. The lack of clearly define training requirements will negatively impact the effective implementation of these standards nationwide.

With the less prescriptive nature of the rules, Agreement States are being required to adopt rules that are viewed as inadequate. Without adequate didactic training, an individual's knowledge of basic radiation safety physics, radiation biology, and radiopharmaceutical chemistry may be lacking. Agreement States are concerned that by using less prescriptive rules, they may likely compromise their citizens to individuals who have not received adequate radiation safety training. In the interest of public health and safety, clearly defined and specified didactic training hours must be codified.

Currently, Agreement States review all third party didactic radiation safety training programs. For example, even though the NRC changed the training and experience criteria for nuclear pharmacists some years ago, Agreement States have continued to use the previous criteria for didactic training (200 hours) when reviewing the adequacy of a new program. As a result, all current nuclear pharmacists have received at least 200 hours of didactic training in the required subject matter. Were the revised rules to be adopted under compatibility B requirements, it is possible that not all didactic training programs would be reviewed using the same criteria, and most likely this would result in a training program not being universally accepted by all Agreement States. Specifying the minimum number of didactic training hours in the rule assures consistency and uniformity in the review of these programs, as well as resulting in uniform and consistent acceptance, in all states, of an approved didactic training program.

Petition for Rulemaking: Amending Training and Education Requirements in Sections of 10 CFR Part 35.

OAS presents this petition for rulemaking within its natural progression to represent the collective principles of its members regarding regulatory standards. Attached is a copy of the OAS Position Statement signed by 30 of the Agreement States in support of this Petition for Rulemaking.

V. CONCLUSION

The proposed amended sections of 10 CFR Part 35 will provide a formal, more structured approach to ensure consistent implementation of the rules nationwide. Defined and specified didactic training hours and supervised clinical training hours will better ensure adequate radiation safety training for Authorized Users and Authorized Nuclear Pharmacists. Therefore, radiation safety will be improved for the licensees, authorized users, the patients, occupationally exposed workers and the public.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

RECEIVED
JUL 16 2004
U.S. Dept. of Health
Human Control and Emergency

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

The revised training and experience requirements specified in 35.55 (Authorized Nuclear Pharmacists), 35.290 (Authorized Users for Imaging and Localization Studies), and 35.390 (Authorized Users for unsealed byproduct material which requires a written directive) include completion of 700 hours of training and experience. The revised training and experience requirements specified in 35.190 (Authorized Users for uptake, dilution and excretion studies) include completion of 60 hours of training and experience. These sections require said training and experience to include "classroom and laboratory training" and supervised "work experience"; however, there is no specified breakdown, or division, of these hours. Previously, the rules did specify a breakdown of hours between classroom and laboratory training and supervised work experience.

OAS supports its membership in defining and implementing consensus standards on the medical use of radionuclides in the Agreement States that (respective to the October 24, 2002 revision of Part 35):

- better ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists;
- specify the acceptable breakdown of didactic and supervised clinical training hours; and,
- improve and ensure consistency and uniformity of training requirements.

Since radiation safety is the goal of any related regulation, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety, that person cannot effectively supervise the safe use of radioactive material.

By not specifying a minimum number of didactic training hours:

- Radiation safety is likely compromised, leading to a weakening of the effectiveness of Part 35 to adequately assure the radiation safety of the patient, the occupationally exposed worker, and the public; and,
- The effort to develop a consistent and uniform set of standards has been weakened.

The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

OAS presents this position statement within its natural progression to represent the collective principles of its members regarding regulatory standards. As a leader in nationwide radiation safety, OAS also seeks to facilitate effective participation of Agreement States in the National Materials Program.

By my signature below, I certify that I am a member of the OAS and confirm my agreement with this position paper. Further, I petition the NRC for a rulemaking to include a breakdown of didactic and supervised clinical hours required in the alternative training pathways for authorized nuclear pharmacists (35.55) and authorized users (35.190, 35.290, and 35.390).

Kathryn E. Whitley 7/13/04
Name and Position

Alabama
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

RECEIVED
JUL 26 2004

Ark. Dept. of Health
Radiation Control and Emergency

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Since radiation safety is the goal of any related regulation, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety, that person cannot effectively supervise the safe use of radioactive material.

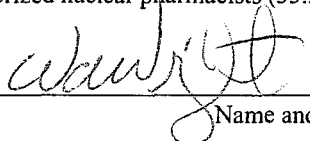
By not specifying a minimum number of didactic training hours:

- Radiation safety is likely compromised, leading to a weakening of the effectiveness of Part 35 to adequately assure the radiation safety of the patient, the occupationally exposed worker, and the public; and,
- The effort to develop a consistent and uniform set of standards has been weakened.

The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

OAS presents this position statement within its natural progression to represent the collective principles of its members regarding regulatory standards. As a leader in nationwide radiation safety, OAS also seeks to facilitate effective participation of Agreement States in the National Materials Program.

By my signature below, I certify that I am a member of the OAS and confirm my agreement with this position paper. Further, I petition the NRC for a rulemaking to include a breakdown of didactic and supervised clinical hours required in the alternative training pathways for authorized nuclear pharmacists (35.55) and authorized users (35.190, 35.290, and 35.390).

 Prog Mgr/RSM/IA Arkansas

Name and Position

State

7/20/04

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS) POSITION PAPER AND PETITION FOR RULEMAKING

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

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OAS supports its membership in defining and implementing consensus standards on the medical use of radionuclides in the Agreement States that (respective to the October 24, 2002 revision of Part 35):

- better ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists;
- specify the acceptable breakdown of didactic and supervised clinical training hours; and,
- improve and ensure consistency and uniformity of training requirements.

Since radiation safety is the goal of any related regulation, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety, that person cannot effectively supervise the safe use of radioactive material.

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Don Kuhl ARRA

Name and Position

7/20/04
State

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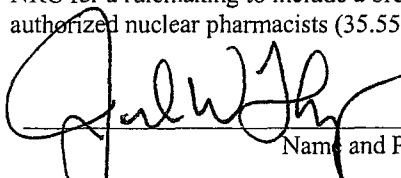
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The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

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 Program Leader
Name and Position


State

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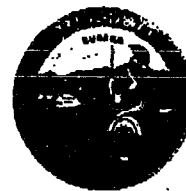
Kim Chubbuck, Health Physicist
Name and Position

Arkansas
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



State of California—Health and Human Services Agency
Department of Health Services



SANDRA L. SHEWRY
Director

ARNOLD SCHWARZENEGGER
Governor

FACSIMILE COVER SHEET

Radiologic Health Branch
Mail Stop 7610
P. O. BOX 997414
Sacramento, CA 95899-7414

Phone: (916) 327-5106
Fax: (916) 440-7999

DATE: 8/03/04

TOTAL NUMBER OF PAGES INCLUDING COVER SHEET: 2

TO: Jared W. Thompson

COMPANY: OAS

PHONE: 501 1061-2849 FAX: ()

FROM: Ed Bailey

PHONE: (916) 440-7899 FAX: ()

☐ URGENT!!!

☐ PER YOUR REQUEST

☐ PLEASE COMMENT

COMMENTS: _____

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AUG 04 2004

P.O. Box 997414, Mail Stop 7610
Sacramento, CA 95899-7414
(916) 327-5106, Fax (916) 440-7999
www.dhs.ca.gov/rhb

Ark. Dept. of Health
Radiation Control and Emergency Mgmt.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS) POSITION PAPER AND PETITION FOR RULEMAKING

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

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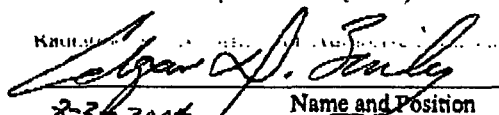
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 Karen A. Bailey, CHIEF CALIFORNIA RAD. HEALTH BRANCH, CALIFORNIA
 Name and Position

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Radiation Control and Emergency Mgmt.

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Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

AUG 04 2004

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Carol J. Buehler
 Name and Position

Hazardous Materials & Waste Management Division

Colorado
 State

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RECEIVED

AUG 04 2004

Ark. Dept. of Health
 Radiation Control and Emergency

REC'D AUG 04 2004



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Will A. Pasnetto BUREAU CHIEF
Name and Position

FLORIDA RECEIVED
State

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Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Ark. Dept. of Health
Radiation Control and Emergency Mgmt.

Underley
Georgia

Jared Thompson

From: Cynthia Sanders [CSanders@dnr.state.ga.us]
Sent: Thursday, July 29, 2004 4:28 PM
To: Jared Thompson
Subject: RE: OAS Position Statement

Jared,

I spoke with David Walters regarding the OAS Position Statement. At this time, I am still not comfortable signing it. I prefer to hold off on this until further discussions at the OAS annual meeting.

Cynthia Sanders

>>> "Jared Thompson" <jwthompson@HealthyArkansas.com> 7/26/2004 10:51:20 AM >>>

> To: Members of the Organization of Agreement States (OAS)
>

Please review the attached Proposed OAS Position Statement on Part 35 Didactic Training Hours. Your response regarding this Position Statement is important. The OAS Board would like to present as many signed statements to the Commission on August 17, 2004. This effort at unity will strengthen our standing with NRC staff and the Commission.

Please return the signed Position Statement to me ASAP. You can fax a copy to me at 501-661-2849, but please mail your signed original. The Part 35 Ad Hoc Committee will be contacting you, if we do not receive a response. We are looking for 100% response from Director Members.

If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!!!!!

Jared Thompson

> On May 26, 2004, the OAS held a meeting in conjunction with the CRCPD
> meeting in Bloomington, Minnesota to discuss Part 35 the didactic training
> issue. Jared Thompson, OAS Chair-Elect facilitated the meeting, where 24 of
> the 33 Agreement States were represented. A consensus opinion was reached
> that a minimum number of didactic hours should be specified for Authorized
> Nuclear Pharmacists and the Authorized Users of 35.100, 35.200 and 35.300
> materials. It was also agreed that the OAS should petition the NRC for
> rulemaking on Part 35 to provide more consistent and uniform training rules.

>
> Those in attendance at the May 26 meeting determined that OAS should
> complete the following action items:
> -- Finalize a position paper for developing consensus among the 33 Agreement
> States regarding the need for establishment of a minimum number of didactic
> training hours for Authorized Nuclear Pharmacist and Authorized Users of
> 35.100, 35.200 and 35.300 materials.
> -- Include in the position paper a petition for rulemaking to the NRC
> regarding the establishment of a minimum number of didactic training hours
> for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and
> 35.300 materials.

>
> In accordance with these action items, the OAS Part 35 Ad Hoc Working Group
> completed a position statement that integrated the petition for rulemaking.

>
> Please review the attached Position Statement. Your input is requested.
> Please read the statement, and if you agree with its declarations,
> please complete the portion that petitions NRC for rulemaking
> and send to Jared Thompson at the address indicated on the form. Please
> send to Jared no later than July 30, 2004. The OAS Executive Board will
> deliver the position statement and petitions to the NRC Commissioners during
> our briefing with them on August 17, 2004. Time is of the essence.

AUG 02 2004



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

Ark. Dept. of Health
 Radiation Control and Emergency Mgr.

**Regarding 10CFR Part 35 Mandated
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David H. Wright - Asst Director TBWA
 Name and Position

Ark
 State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

Ark. Dept. of Health
Radiation Safety
June 26 2004

JUN 26 2004

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Donald A. Slater, Chief, BRH

Name and Position

Idaho

State

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Organization of Agreement States

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**Regarding 10CFR Part 35 Mandated
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JUL 23 2004
Radiat. Ark. Dept. of Health

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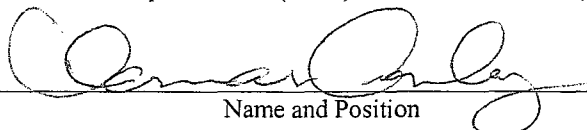
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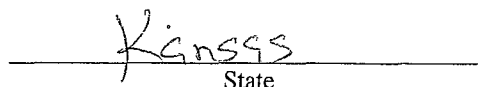
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Name and Position


State

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Robert J. Pherson Program Administrator
Name and Position

Kentucky
State

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By not specifying a minimum number of didactic training hours:

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Michael E. Amey, CRCPD DIRECTOR MEMBER
Name and Position

7/9/04
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

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JUL 30 2004

**Ark. Dept. of Health
Radiation Control and Emergency Mgmt.**

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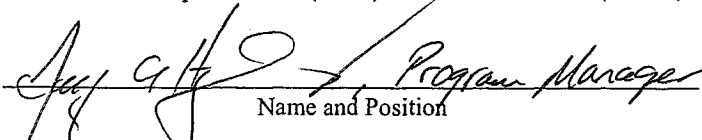
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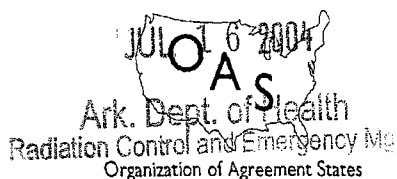
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Name and Position


State

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Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

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Robert Walker, Director
Ark Radiation Control Program
Name and Position

July 12/04
State

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Organization of Agreement States

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Robert W. Goff, Director Radiological Health
Name and Position

Mississippi
State

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Organization of Agreement States

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Training and Experience Requirements
and Medical Didactic Training Hours**

**Ark. Dept. of Health
Radiation Control and Emergency Mgmt.**

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Julia Schmidt Radiation Control Program Manager Nebraska
Name and Position State

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KENNY C. GUINN
Governor

MICHAEL J. WILLDEN
Director



YVONNE SYLVA
Administrator

BRADFORD LEE, M.D.
State Health Officer

STATE OF NEVADA
DEPARTMENT OF HUMAN RESOURCES
HEALTH DIVISION
BUREAU OF HEALTH PROTECTION SERVICES

FACSIMILE TRANSMISSION COVER SHEET

☐ Bureau Administration
1179 Fairview Drive, Ste. 201
Carson City, NV 89701-5405
(775) 687-6353
Fax (775) 687-5197

☐ Public Health Engineering
1179 Fairview Drive, Ste. 101
Carson City, NV 89701-5405
(775) 687-4754
Fax (775) 687-5699

☐ Drinking Water
State Revolving Fund
1179 Fairview Drive, Ste. 204
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-3218

☐ Radiological Health
1179 Fairview Drive, Ste. 102
Carson City, NV 89701-5405
(775) 687-5394
Fax (775) 687-5751

☐ Environmental Health
1179 Fairview Drive, Ste. 104
Carson City, NV 89701-5405
(775) 687-4750
Fax (775) 687-5751

☐ Health Protection Services
620 Belrose Street, Ste. 101
Las Vegas, NV 89107
Engineering and Food
(702) 486-5068
Radiological Health
(702) 486-5280
Fax (702) 486-5024

Health Protection Services
850 Elm Street
Elko, NV 89801-3349
(775) 753-1138/1140

Health Protection Services
475 W. Haskell Street, Rm. 38
Winnemucca, NV 89445
(775) 623-6588

Health Protection Services
155 N. Taylor Street, Ste. 199
Fallon, NV 89406-3324
(775) 423-2281
Fax (775) 428-0259

Health Protection Services
P.O. Box 151210
Ely, NV 89315
(775) 289-3325

Health Protection Services
P.O. Box 667
Tonopah, NV 89049-0667
(775) 482-3997

Date: 7-26-04

Content: pages (including cover sheet)

To: Jared Thompson

501-661-2849

From: Marshall, Nevada

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JUL 26 2004

Re:

Ark. Dept. of Health
Radiation Control and Emergency Mgmt.

Authorized signature: [Signature]

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"Building and Strengthening Public Health through Communication and Partnerships"



Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

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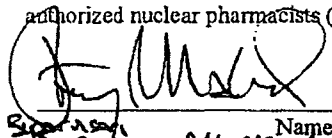
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Name and Position
Stanley R. Marshall

Nevada July 26, 2004
State

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Organization of Agreement States

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Dennis P. O'Dowd

Dennis P. O'Dowd, Acting Administrator
Radiological Health Section
Division of Public Health Services

Name and Position

New Hampshire

State

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Organization of Agreement States

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Name and Position

Bureau Chief

New Mexico
State

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**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

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By not specifying a minimum number of didactic training hours:

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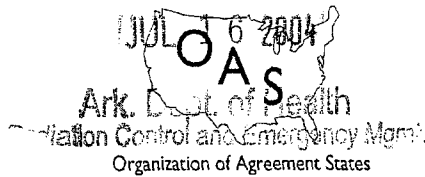
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Stanley Fitch, Health Physicist
[Signature] 7-6-04
Name and Position

New Mexico
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

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Margaret M. Loydal - RAM licensing
Name and Position

New Mexico Radiation Control Bureau
State

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Organization of Agreement States

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Adela Salame-Alfiez

Name and Position

New York State Dept of Health

State

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Organization of Agreement States

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Ark. Dept. of Health
Radiation Control and Emergency Man.

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Name and Position

DIRECTOR OFFICE OF
RAD. HEALTH

NEW YORK CITY - N.Y. AGREEMENT
State

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Organization of Agreement States

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JUL 30 2004
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Ark. Dept. of Health

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Name and Position

CLAYTON BRADT PRINCIPAL RADIOPHYSICIST

NYS DEPT. OF LABOR

State

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FAX

TO:

Jared ThompsonFAX #: 501-661-2849

FROM:

Beverly O. HallDATE: 7-26-04Page(s): 2, Including cover sheet.

Comments:

OAS Position Statement

Radiation Protection Section
1645 Mail Service Center
Raleigh, NC 27699-1645
☎: (919) 571-4141
☎: (919) 571-4148

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JUL 26 2004

Ark. Dept. of Health
Radiation Control and Emergency Mgmt.



Organization of Agreement States

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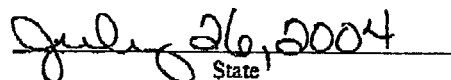
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Name and Position


State

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Jared Thompson

From: Beverly Hall [beverly.hall@ncmail.net]
Sent: Monday, July 26, 2004 10:25 AM
To: Jared Thompson
Cc: Stanley Fitch
Subject: Re: OAS Position Statement

I am signing this Position statement, however, we are checking with the NC Board of Pharmacy to ensure we have the authority and also, that there will be no conflicts with the Nuclear Pharmacist requirements.

Beverly Hall

Jared Thompson wrote:

To: Members of the Organization of Agreement States (OAS)

Please review the attached Proposed OAS Position Statement on Part 35 D

Please return the signed Position Statement to me ASAP. You can fax a

If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!!!!!

Jared Thompson

On May 26, 2004, the OAS held a meeting in conjunction with the CRCPD meeting in Bloomington, Minnesota to discuss Part 35 the didactic training issue. Jared Thompson, OAS Chair-Elect facilitated the meeting, where 24 the 33 Agreement States were represented. A consensus opinion was reached that a minimum number of didactic hours should be specified for Authorized Nuclear Pharmacists and the Authorized Users of 35.100, 35.200 and 35.300 materials. It was also agreed that the OAS should petition the NRC for rulemaking on Part 35 to provide more consistent and uniform training rule

Those in attendance at the May 26 meeting determined that OAS should complete the following action items:

- Finalize a position paper for developing consensus among the 33 Agreement States regarding the need for establishment of a minimum number of didactic training hours for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and 35.300 materials.
- Include in the position paper a petition for rulemaking to the NRC regarding the establishment of a minimum number of didactic training hours for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and 35.300 materials.

In accordance with these action items, the OAS Part 35 Ad Hoc Working Group completed a position statement that integrated the petition for rulemaking

Please review the attached Position Statement. Your input is requested.

7/26/2004

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Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

AUG 02 2004

Ark. Dept. of Health
 Radiation Control and Emergency Med.

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Jerry Olson Director, Air Quality Div.

Name and Position

North Dakota

State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

Jared Thompson

From: Robert Owen [ROWEN@gw.odh.state.oh.us]
Sent: Wednesday, August 04, 2004 4:22 PM
To: Jared Thompson
Cc: MHOWARD@gw.odh.state.oh.us
Subject: RE: OAS Position Statement

OHIO

NO

Jared, I believe more work needs to be done among ourselves and in conjunction with NRC in order to flush out what the training hours needs to be. I certainly don't support moving forward with a rule petition, since that demonstrates a final position on the part of OAS. Even among ourselves there are differences of opinion.

I am also unconvinced that we are at a point of arriving at a final position statement without studying the issues via a working group in a cooperative effort, resulting in a position paper that is adoptable by all of OAS. I believe a consensus position is what the National Materials Program would dictate, and that includes NRC at the table, ultimately.

I realize that NRC went ahead and adopted their standard pursuant to ACMUI and not necessarily factoring in OAS concerns. I'm not sure on that point. However, I don't believe we should reciprocate.

I'm looking forward to further discussion of the matter at the OAS annual meeting. Hopefully, we can arrive at a true consensus position on the matter. If not, then further work needs to be done in that direction.

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Thanks for the opportunity to comment.

Bob

AUG 06 2004

-----Original Message-----

From: ODH_REMOTE.GWIA."jwthompson@HealthyArkansas.com"

Sent: Monday, July 26, 2004 10:51 AM

To: Robert Owen; agodwin@arra.state.az.us; asa01@health.state.ny.us;
bayoungb@gw.dec.state.ny.us; beverly.hall@ncmail.net; bill_passetti@doh.state.fl.us;
Bob.Walker@state.ma.us; clayton.bradt@labor.state.ny.us; csanders@dnr.state.ga.us;
dfinerfrock@utah.gov; dflater@idph.state.ia.us; dodowd@dhhs.state.nh.us;
Eastvold@iema.state.il.us; EBailey@dhs.ca.gov; eddie.nanney@state.tn.us;
gary.robertson@DOH.WA.GOV; gmiskin@health.nyc.gov; jackf@doh.state.ri.us;
jay.hyland@state.me.us; john_parker@nmenv.state.nm.us; julia.schmitt@hhss.state.ne.us;
kwangler@state.nd.us; kwhatley@adph.state.al.us; michael.henry@la.gov;
Mike.Broderick@deq.state.ok.us; okelletp@dhec.sc.gov; rfletcher@mde.state.md.us;
rgoff@msdh.state.ms.us; Richard.Ratliff@tdh.state.tx.us; robertl.johnson@mail.state.ky.us;
sjablons@tnrcc.statetx.us; smarshall@nvhd.state.nv.us; Steve.Tarlton@state.co.us;
tconley@kdhestate.ks.us; william_floyd@nmenv.state.nm.us
Cc: dflater@state.al.us; Edwin.L.Wright@state.or.us; kenneth.weaver@state.co.us;
kwiebeck@HealthyArkansas.com; stanley_fitch@nmenv.state.nm.us
Subject: RE: OAS Position Statement

Ark. Dept. of Health
Radiation Control and Emergency Med

> To: Members of the Organization of Agreement States (OAS)
>

Please review the attached Proposed OAS Position Statement on Part 35 Didactic Training Hours. Your response regarding this Position Statement is important. The OAS Board would like to present as many signed statements to the Commission on August 17, 2004. This effort at unity will strengthen our standing with NRC staff and the Commission.

Please return the signed Position Statement to me ASAP. You can fax a copy to me at 501-661-2849, but please mail your signed original. The Part 35 Ad Hoc Committee will be contacting you, if we do not receive a response. We are looking for 100% response from Director Members.

If you have already responded.....THANK YOU!!!!!!!!!!!!!!!!!!!!!!

Jared Thompson

> On May 26, 2004, the OAS held a meeting in conjunction with the CRCPD
> meeting in Bloomington, Minnesota to discuss Part 35 the didactic training
> issue. Jared Thompson, OAS Chair-Elect facilitated the meeting, where 24 of
> the 33 Agreement States were represented. A consensus opinion was reached
> that a minimum number of didactic hours should be specified for Authorized
> Nuclear Pharmacists and the Authorized Users of 35.100, 35.200 and 35.300
> materials. It was also agreed that the OAS should petition the NRC for
> rulemaking on Part 35 to provide more consistent and uniform training rules.
>
> Those in attendance at the May 26 meeting determined that OAS should
> complete the following action items:
> -- Finalize a position paper for developing consensus among the 33 Agreement
> States regarding the need for establishment of a minimum number of didactic
> training hours for Authorized Nuclear Pharmacist and Authorized Users of
> 35.100, 35.200 and 35.300 materials.
> -- Include in the position paper a petition for rulemaking to the NRC
> regarding the establishment of a minimum number of didactic training hours
> for Authorized Nuclear Pharmacist and Authorized Users of 35.100, 35.200 and
> 35.300 materials.
>
> In accordance with these action items, the OAS Part 35 Ad Hoc Working Group
> completed a position statement that integrated the petition for rulemaking.
>
> Please review the attached Position Statement. Your input is requested.
> Please read the statement, and if you agree with its declarations,
> please complete the portion that petitions NRC for rulemaking
> and send to Jared Thompson at the address indicated on the form. Please
> send to Jared no later than July 30, 2004. The OAS Executive Board will
> deliver the position statement and petitions to the NRC Commissioners during
> our briefing with them on August 17, 2004. Time is of the essence.
>
>
> Jared W. Thompson, Chair-Elect
> Organization of Agreement States
>
> Arkansas Department of Health
> Radioactive Materials Program
> 4815 W. Markham, Mail Slot 30
> Little Rock, Arkansas 72205
> 501-661-2173
> 501-661-2849 (fax)
> Do not mistake for conspiracy and intrigue what can best be explained by
stupidity and incompetence.
>
> <<Didactic_Training_Position_Statement.pdf>>

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of the intended recipient and may contain
privileged, sensitive, or protected health
information. If you are not the intended
recipient, be advised that any unauthorized
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Organization of Agreement States, Inc. (OAS)
POSITION PAPER AND PETITION FOR RULEMAKING

**Regarding 10CFR Part 35 Mandated
Training and Experience Requirements
and Medical Didactic Training Hours**

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Pamela L Bishop ESTV
Name and Position

Oklahoma
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

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Organization of Agreement States

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Ark. Dept. of Health
 Radiation Control and Emergency Med.

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Edin Thight Mgr

7/30/04

Name and Position

RADIOACTIVE MATERIALS LICENSING

OREGON

State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.



Organization of Agreement States

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POSITION PAPER AND PETITION FOR RULEMAKING

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JUL 19 2004
Ark. Dept. of Health

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Maio Stockel, Chief, Rad. Control Agency
Name and Position

Rhode Island
State

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Organization of Agreement States

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Name and Position

State

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Organization of Agreement States

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Ark. Dept. of Health
Radiation Control and Emergency Medicine
July 30 2004

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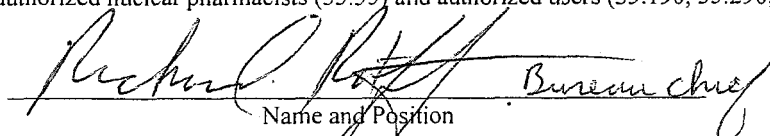
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Name and Position

Texas
State

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Organization of Agreement States

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July 9 2004
Ark. Dept. of Health
Control and Emergency Mgmt.

Organization of Agreement States, Inc. (OAS)
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Lauren Ramsey, Director
Name and Position

Tennessee (Div. of Radiological Hlth)
State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.

FAX

DATE:

7-26-04

TIME:

PAGES:

Two

TO:

Jared Thompson

FROM:

Craig Jones

Radioactive Materials Program
Arkansas Dept. of Health
FAX 501/661-2136

**State of Utah**

Department of Environmental Quality
Division of Radiation Control

168 North 1950 West
Salt Lake City, Utah 84118

Oliver S. Walker

Governor

Dianne R. Nielson, Ph.D.

Executive Director

Dana L. Fournier

Director

(801)596-4250 VOX

(801)533-4097 FAX

(801)596-4414 TDD

SUBJ:

10 CFA 35

Position Statement

COMMENTS

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JUL 26 2004

Ark. Dept. of Health
Radiation Control and Emergency Mgmt.



Organization of Agreement States

Organization of Agreement States, Inc. (OAS)
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Attorney General
Name and Position

Utah
State

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Organization of Agreement States, Inc. (OAS)
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AUG 02 2004

Ark. Dept. of Health
 Radiation Control and Emergency Mgmt.

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Gary Robertson Director
 Name and Position

WA

State

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Organization of Agreement States

Organization of Agreement States, Inc. (OAS) POSITION PAPER AND PETITION FOR RULEMAKING

Regarding 10CFR Part 35 Mandated Training and Experience Requirements and Medical Didactic Training Hours

The Nuclear Regulatory Commission (NRC) revised 10CFR Part 35, effective October 24, 2002, to make the rule more risk-informed and performance based. The revised rules are less prescriptive, and rely more on the knowledge and performance of Radiation Safety Officers, Authorized Users, Authorized Medical Physicists and Authorized Nuclear Pharmacists to maintain adequate radiation safety programs. Therefore the safe use of radioactive material in medicine now relies primarily on the various training and experience requirements specified in Part 35.

The revised training and experience requirements specified in 35.55 (Authorized Nuclear Pharmacists), 35.290 (Authorized Users for Imaging and Localization Studies), and 35.390 (Authorized Users for unsealed byproduct material which requires a written directive) include completion of 700 hours of training and experience. The revised training and experience requirements specified in 35.190 (Authorized Users for uptake, dilution and excretion studies) include completion of 60 hours of training and experience. These sections require said training and experience to include "classroom and laboratory training" and supervised "work experience"; however, there is no specified breakdown, or division, of these hours. Previously, the rules did specify a breakdown of hours between classroom and laboratory training and supervised work experience.

OAS supports its membership in defining and implementing consensus standards on the medical use of radionuclides in the Agreement States that (relative to the October 24, 2002 revision of Part 35):

- better ensure adequate radiation safety training for Authorized Users, Radiation Safety Officers and Authorized Nuclear Pharmacists;
- specify the acceptable breakdown of didactic and supervised clinical training hours; and,
- improve and ensure consistency and uniformity of training requirements.

Since radiation safety is the goal of any related regulation, consideration must be given to the methods by which an Authorized User, Radiation Safety Officer or Authorized Nuclear Pharmacist receives radiation safety training. The majority of basic radiation safety principles are learned in the didactic portion of training, not with "work experience". If an Authorized User or Radiation Safety Officer is not adequately trained in radiation safety, that person cannot effectively supervise the safe use of radioactive material.

By not specifying a minimum number of didactic training hours:

- Radiation safety is likely compromised, leading to a weakening of the effectiveness of Part 35 to adequately assure the radiation safety of the patient, the occupationally exposed worker, and the public; and,
- The effort to develop a consistent and uniform set of standards has been weakened.

The Agreement States have regulatory authority over nearly 80% of the byproduct licensees nationwide. It is incumbent upon the Agreement States to assure adequate radiation safety under these licenses. The membership of the OAS has expressed profound concern that by being required to accept diminished didactic training requirements, the Agreement States are forced to the possible jeopardy of subjecting their citizens to users who have not received adequate radiation safety training.

OAS presents this position statement within its natural progression to represent the collective principles of its members regarding regulatory standards. As a leader in nationwide radiation safety, OAS also seeks to facilitate effective participation of Agreement States in the National Materials Program.

By my signature below, I certify that I am a member of the OAS and confirm my agreement with this position paper. Further, I petition the NRC for a rulemaking to include a breakdown of didactic and supervised clinical hours required in the alternative training pathways for authorized nuclear pharmacists (35.55) and authorized users (35.190, 35.290, and 35.390).

Paul Schmidt, Chief, RPS

Name and Position

Wisconsin

State

Please forward the completed form no later than July 30, 2004 to Jared W. Thompson, Radioactive Materials Program, Arkansas Department of Health, 4815 West Markham Street, Slot #30, Little Rock, Arkansas 72205-3867.